



K073222

APR - 9 2008

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
SPECIALTY NEEDLE**

Regulatory Affairs Contact: Muhamad Ansari
Busse Hospital Disposables
PO Box: 11067
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Date Summary Revised: April 4, 2008

Product Trade Name: Specialty Needles (Spinal Needle, Pencil Point, Epidural Needle)

Common Name: Anesthesia Conduction Needle.

Classification: Class II, 21 CFR 868.5150

Product Code: BSP

Predicate Device: Busse Spinal Needle - (K061394)

Device Description: Anesthesia conduction needles consist of different styles. All the needles consist of a plastic or K-Resin hub connected to a stainless steel cannula. Some of the needles have stylets made of the same steel whereas others have stylets made of plastic. Some of the needles have wings, which can be attached to the hub for more stability depending on user procedure.
The needles have been categorized as following:
1. Spinal Needles (Quincke)
2. Pencil Point Spinal Needle (Whitacre)
3. Epidural Needles (Tuohy & Hustead)

The differences between the styles of needles are the tip of the needle, which is pencil-point-tip (Whitacre), curved and sharp needle (Tuohy) or sharp needle tip (Quincke).

Needle Style	Gage Size Range	Length Range
Spinal Needle (Quinke)	18g to 27g	1 ½" to 6"
Pencil Point Spinal Needle (Whitacre)	18g to 27g	1 ½" to 6"
Epidural Needle (Tuohy, & Hustead)	16g to 25g	1 ½" to 6"

These needles will be provided as sterile, single use, disposable devices. They will be packaged individually or included in regional anesthesia trays.

Intended Use:

Specialty needles (Spinal Needle, Pencil Point Needle, and Epidural Needle) are intended for the transient delivery of anesthetics to provide regional anesthesia or to facilitate placement of an epidural catheter.

Summary of Testing: All materials used in the fabrication of the specialty needles were evaluated through biological qualification safety tests. The biocompatibility tests performed were Elution Test, Systemic Injection Test, Rabbit Pyrogen Test, Intracutaneous Injection Test, Kligman Maximization Test.

These materials have met the testing requirements and were found to be acceptable for the intended use.

Summary of tests performed to prove the substantial equivalence of the Specialty Needles with the predicate device:

1. Same intended use
2. Same material with exception of needle hub
3. Same flow rate
4. Same bonding strength

Technological Characteristics:

[21 CFR 807.92(a)(6)]

The subject device has the same Technological Characteristics as a legally marketed predicate device.

Conclusion:

[21 CFR 807.92(b)(3)]

The above statements are accurate representations of the device Busse intends to market.

All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2008

Mr. Muhamad Ansari
Director of Regulatory Affairs
Busse Hospital Disposables, Incorporated
75 Arkay Drive
Hauppauge, New York 11788

Re: K073222
Trade/Device Name: Specialty Needles
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: March 5, 2008
Received: March 10, 2008

Dear Mr. Ansari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K073222

Device Name: Specialty Needles.

Indication for Use: specialty needles – Spinal Needle, Pencil Point Needle, and Epidural Needle – are intended for the transient delivery of anesthetics to provide regional anesthesia or to facilitate placement of an epidural catheter.

Prescription Use x
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073222